A critical appraisal of "A Single-Blinded Randomized Placebo-Controlled Clinical Trial of Manipulation and Mobilization in the Treatment of Morton's Neuroma"

By

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In partial fulfillment of the

requirements for the course:

PT 7240 Evidence-Based Practice in Physical Therapy

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November, 2019

Abstract

A research group from Durban University of Technology in Durban, South Africa conducted a study on patients with Morton's neuroma to analyze the efficacy of manipulation and mobilization techniques on the pain levels of the patients. 40 subjects with Morton's neuroma were divided in two groups. The control group received foot and ankle manipulation and mobilization while the placebo group received de-tuned ultrasound. Each subject did not know which group they were in, and each group received their respective treatments twice a week for three weeks, and then their pain levels were re-evaluated based on questionnaires and pain pressure tolerance. This paper analyzes the research performed and discusses the pros and cons through the introduction, materials and methods, results, and discussion. It then evaluates the research study as a whole and discusses changes that could be made to improve the research study.

Key words

Morton's neuroma, Morton's neuroma treatment, Morton's neuroma manipulation

Introduction

Morton's neuroma is a condition that has yet to find a definitive cure. An individual with this pain can try physical therapy, receive steroid injections, they can put padding in their shoes, or they can have surgery. Of the options listed, none have a 100% success rate. Without a gold standard of treatment, a patient with a Morton's neuroma who is sent to physical therapy will receive different treatment at different clinics, but treatment can still prevent the need for surgery. This poses the question what is the effectiveness of physical therapy intervention to prevent surgery in patients with Morton's neuroma? If manual therapy techniques can be narrowed down so physical therapists can have a "gold standard" treatment for patients with Morton's neuroma, more patients could avoid trying surgery to potentially alleviate their pain.

Methods

NCBI and PubMed databases were used in the initial search because I thought they would give me the most relevant sources. Additionally, the Angelo State University Porter Henderson Library database was used to access various outside links. Keywords used for the search include: "Morton's neuroma physical therapy", "Morton's neuroma manual therapy", "non-surgical treatment morton's neuroma", "Morton's neuroma management", "Morton's neuroma treatment" "metatarsalgia treatment", and "Morton's neuroma physical therapy techniques". I limited my search to scholarly (peer reviewed) journals because in my past research experience, this produces the most reliable and most dependable results. Additionally, with each of the above terms searched, I narrowed down my search by changing the search field from all to "SU Subject Terms". For the NCBI database, I set a year limit on my results. When I searched "Morton's neuroma treatment", I noticed the number of journal entries for this topic started to boom in the early 2000s, so I adjusted my publication date settings to 2005-present. For this search I

excluded the population that had tried surgery for pain, as well as those who used steroid injections to try to alleviate the pain. I only included individuals who had not had surgery and who wanted to try non-invasive manual therapy techniques. With these criteria, my results ranged from 4-400.

I chose the article "A Single-Blinded Randomized Placebo-Controlled Trial of Manipulation and Mobilization in the Treatment of Morton's Neuroma" by Neetu Govender et. al. at Durban University of Technology in Durban, South Africa. This article is from the Journal of the American Chiropractic Association and was published in April 2007. I chose this article for critical appraisal because it has a lot of positive potential, but also a few notes to pose skepticism.

Results

Summary of the study

Neetu Govender, et. al. performed a study with 40 subjects who had Morton's neuroma and randomly assigned 20 subjects (experimental group) to receive foot and ankle manipulation and mobilization while the other 20 (control group) received de-tuned ultrasound therapy. Subjects received their treatment twice a week for three weeks, and outcomes were measured based on a pain rating scale (NRS), pain questionnaire, foot function index-pain, foot function index-disability, Algometer pain pressure threshold, and pain pressure tolerance. The results of this experiment concluded there was a statistically significant improvement in pain levels with the experimental group compared to the control group, as well as there was a statistically significant improvement in algometry pain pressure threshold levels in the experimental compared to the control group.

Appraisal of the study introduction

The introduction provides more than sufficient information on the background of Morton's neuroma including what it is, prevalence, and what other research has shown about it. The literature review concludes there have been successful chiropractic treatment and successful research studies involving manipulative and mobilization techniques. These other studies are used by Govender et al. to evaluate the effectiveness of the latter and has formed a sound rationale for the study because of them. The introduction has clearly laid out the independent variable (the use of manipulation and mobilization) and the dependent variable (pain level for the patients).

The introduction is detailed, but some additional information could make it stronger. While there is not one specific cause of Morton's neuromas, some various causes could have been listed. The introduction cites various case reports, the majority of which were published at least 10 years prior to the publication of the research in 2007. While this is considered a newer area of research, the researchers should have sought more recent references than research from 1988 or 1991.

Appraisal of the study methods

The research design is a randomized study. It is a retrospective study because there is a placebo control group, it is longitudinal because the treatments are over a period of 3 weeks, and it is single-blinded. There are two groups in the study, and it is a between-subject design because it compares the experimental group results to those of the control group. The researchers did a good job randomizing the groups by drawing numbers from a container. Another strength was each group received the same amount of treatment, and the instruments/tools used are described in sufficient detail. The interventions used are described in detail and images are also provided, making it easier for anyone who wants to replicate the study to do so.

One of the weaknesses of this study is the research design. A single-blinded study leaves room for the clinician to potentially skew the results and make the placebo group look worse

than the true results, or make the experimental group look like they improved more than the numbers indicate. In future studies, the design should be double-blinded for more reliable data. Another weakness of this study was the algometry used for one of the pain measurements. It is later mentioned that algometry has not been proven valid and reliable for Morton's neuroma measurements.

Appraisal of the study results

The results section has more weaknesses than strengths. One of the strengths is the authors did not go into excessive detail, but rather they were brief with presenting their findings. Another strength of the results is the numbers presented. Instead of only saying what the findings were, the authors included the statistical data, including the p value used and which statistical analysis was run to obtain the values.

A weakness of the results is the organization. There is not a clear organization, rather all the data is thrown at the reader. The authors do not address their research question in their results, and the data they present is not pertaining to their research question. This study is testing the efficacy of what literature says can help treat Morton's neuroma. The results say there is a statistically significant improvement in pain perception that is relevant to the study, but the statistical conclusions do not pertain to testing the efficacy of literature. Another weakness of the results is the statistics presented. The only clinically meaningful statistic is the significant improvement in perceived pain after 6 weeks of treatment. The pain pressure threshold and pain pressure tolerance levels are not a main objective of the study to improve, so they could have been excluded.

Appraisal of the study discussion

Like the results, the discussion also had more weaknesses than strengths. A strength was the positive results of their research. They add at the end of the discussion that their results in addition to current literature helps "support the efficacy of manipulation and mobilization in treatment of Morton's neuroma". The researchers also acknowledged the limitations in their study, including the small sample size and the use of placebo potentially introducing bias to the study. A strength of research is recognizing where you can improve your study in the future.

One weakness of the discussion was the content. Instead of discussing the meaning of the results, the authors added more information about Morton's neuromas that would have fit better in the introduction. They then went on to discuss the limitations of the study in detail while only once mentioning how their findings strengthen literature.

Discussion

This research positively influences current Physical Therapists because it provides some reliable mobilization techniques to apply to patients with Morton's neuroma. While the researchers mention there is not enough evidence to fully support any sort of intervention, this experiment positively answers my clinical question by showing there can be an effective short-term treatment for patients with Morton's neuroma that does not involve surgery.

Overall, I am in favor of using these mobilization techniques. The researchers could have done a few things differently, but it can easily be replicated to see if the same results apply. The design of the study is sound, but most of the negatives came from the information provided in the paper and the way the researchers outlined their paper, not in how they conducted the study. I believe the potential benefits of this treatment method far outweigh the potential risks. Either a patient is going to have significantly improved pain levels, or they will stay the same. This

research has not been proven to increase the pain levels, so there is not a true “risk” in participating in this study for patients with Morton’s neuroma. I believe this research could be improved if it were performed double-blinded to eliminate bias.

I believe this evidence can be applied to future patients. While this area of research is still growing, there is not any sufficient evidence to fully support the effectiveness of any other non-surgical interventions for Morton’s neuroma. This research has promising results, and the images provided make it easy to apply the same manipulation and mobilization techniques to my future patients. These techniques can easily be performed in the clinic as they do not require any instrumentation, and the research does not indicate it will increase pain levels, so the patient does not have anything to risk.

Overall, this paper had some negatives in the lay-out of it, but the information is of good quality. The research study is mostly sound, apart from the design being single-blinded. If the exact same study were to be conducted in a double-blind manner, the results would be more reliable and would further the positive outlook on manipulation and mobilization techniques to treat Morton’s neuroma and save patients the pain, hassle, and expense of surgery.